

REMARKS/ARGUMENTS

Claims 1-7, 9-20, 29-31, 33-37 and 41-53 are pending. Previously withdrawn claims 21-28 and 38-40 have been cancelled. Claims 1 and 29 have been amended. Claims 41-53 have been added. No new matter has been added with the present amendment. Support for the amendment may be found throughout the specification and specifically at page 14 lines 2-31. In the Office Action, the Examiner rejected claims 1-7, 9-20, 29-31 and 33-37 on various grounds. The Applicant responds to each ground of rejection as subsequently recited herein. Reconsideration of this Application and entry of this Amendment is respectfully requested.

35 U.S.C. §102 Rejections

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant the §102(e) rejection, the reference cited by the Examiner must show each and every limitation of the claims in complete detail. The Applicants respectfully assert that the cited reference fails to do so.

A. Claims 1, 2, 6, 12, 14, 29, 31 and 33-35 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Pub No. 2003/0235602 to Schwartz (the Schwartz publication).

This rejection is respectfully traversed. The Applicants submit that the Schwartz publication fails to include each and every element of the Applicants' invention as claimed, as required to maintain a rejection under 35 U.S.C. §102(e). *See* MPEP 2131. The Applicants assert that the Schwartz publication fails to disclose, teach, or suggest:

1) a system for treating a vascular condition comprising a catheter, a stent coupled to the catheter, the stent including a stent framework, a hydrophobic polymeric coating disposed on the stent framework, wherein the polymeric coating comprises a blended matrix of a polysulfone and a styrenic block copolymer, wherein the blended matrix includes a first fraction comprising the polysulfone and a second fraction comprising the styrenic block copolymer, wherein the first fraction is greater than the second fraction and wherein the styrenic block

copolymer has a molecular weight between 200 Daltons and 200,000 Daltons; and a therapeutic agent in contact with the blended matrix, as recited in claim 1; and

2) a drug-polymer coated stent, comprising a stent framework; and a polymeric coating disposed on the stent framework, wherein the polymeric coating comprises a blended matrix of a polysulfone and a styrenic block copolymer; and a therapeutic agent contacting the polymeric coating, wherein the blended matrix comprises a first fraction of the polysulfone and a second fraction of the styrenic block copolymer based on a predetermined elution rate of the therapeutic agent, wherein the ratio of first fraction of polysulfone to second fraction of styrenic block copolymer is selected so the coating has a predetermined hydrophobicity, as recited in claim 29.

The Schwartz publication teaches an implantable or insertable medical device for controlled delivery of a therapeutic agent. Nowhere within the Schwartz publication does it teach hydrophobic polymeric coatings or a coating with a predetermined hydrophobicity as claimed by the Applicants. In fact, nowhere within the Schwartz publication does the terms hydrophobic and hydrophobicity occur. At most, the Schwartz publication teaches a laundry list of polymers that may be mixed together to form a coating without providing any direction. For at least these reasons, the Applicants request the withdrawal of the rejection of independent claims 1 and 29.

Claims 2, 6, 12, 14 and 15 depend from claim 1 and include all of the limitations of that claim. Claims 31 and 33-35 depend from independent claim 29 and include all of the limitations of that claim. For at least this reason claims 2, 6, 12, 14, 15, 31 and 33-35 are allowable over the Schwartz publication. Withdrawal of the rejection of claims 1, 2, 6, 12, 14, 15, 29, 31 and 33-35 under 35 U.S.C. § 102(e) is respectfully requested.

35 U.S.C. §103 Rejections

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. See MPEP 2143. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03.

- B. Claims 3-5 and 30 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the Schwartz publication.

The Applicants traverse this rejection. As stated above in section A, the Schwartz publication does not teach all of the claim limitations of independent claims 1 and 29. Claim 3-5 depends from independent claim 1 and includes all of the elements and limitations of independent claim 1 and, thus, are allowable for at least the same reasons as those stated above for claim 1. Claim 30 depends from independent claim 29 and includes all of the elements and limitations of independent claim 29 and, thus, is allowable for at least the same reasons as those stated above for claim 29. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claims 3-5 and 30 under § 103(a).

- C. Claim 7 has been rejected under 35 U.S.C. §103(a) as being unpatentable over the Schwartz publication in view of US 4,157,960 to Change et al.

The Applicants traverse this rejection. As stated above in section A, the Schwartz publication does not teach all of the claim limitations of independent claim 1. The Change patent does not cure these defects. Claim 7 depends from independent claim 1 and includes all of the elements and limitations of independent claim 1 and, thus, is allowable for at least the same reasons as those stated above for claim 1. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claim 7 under § 103(a).

- D. Claim 9 has been rejected under 35 U.S.C. §103(a) as being unpatentable over the Schwartz publication in view of WO 03/022323 to Pacetti

The Applicants traverse this rejection. As stated above in section A, the Schwartz publication does not teach all of the claim limitations of independent claim 1. The Pacetti publication does not cure these defects. Claim 9 depends from independent claim 1 and includes all of the elements and limitations of independent claim 1 and, thus, is allowable for at least the same reasons as those stated above for claim 1. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claim 9 under § 103(a).

- E. Claim 10 has been rejected under 35 U.S.C. §103(a) as being unpatentable over the Schwartz publication in view of US Pub. No. 2003/0083739 to Cafferata

The Applicants traverse this rejection. As stated above in section A, the Schwartz publication does not teach all of the claim limitations of independent claim 1. The Cafferata publication does not cure these defects. Claim 10 depends from independent claim 1 and includes all of the elements and limitations of independent claim 1 and, thus, is allowable for at least the same reasons as those stated above for claim 1. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claim 10 under § 103(a).

- F. Claim 11 has been rejected under 35 U.S.C. §103(a) as being unpatentable over the Schwartz publication in view of US Pat. No. 6,153,252 to Hossainy

The Applicants traverse this rejection. As stated above in section A, the Schwartz publication does not teach all of the claim limitations of independent claim 1. The Hossainy patent does not cure these defects. Claim 11 depends from independent claim 1 and includes all of the elements and limitations of independent claim 1 and, thus, is allowable for at least the same reasons as those stated above for claim 1. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claim 11 under § 103(a).

- G. Claims 13 and 16-18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the Schwartz publication in view of US Pat. Pub. No. 2003/0083646 to Sirhan et al.

The Applicants traverse this rejection. As stated above in section A, the Schwartz publication does not teach all of the claim limitations of independent claim 1. The Sirhan publication does not cure these defects. Claims 13 and 16-18 depend from independent claim 1 and include all of the elements and limitations of independent claim 1 and, thus, are allowable for at least the same reasons as those stated above for claim 1. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claims 13 and 16-18 under § 103(a).

- H. Claims 19, 20, 36 and 37 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the Schwartz publication in view of US Pat. Pub. No. 2001/0014717 to Hossainy et al.

The Applicants traverse this rejection. As stated above in section A, the Schwartz publication does not teach all of the claim limitations of independent claims 1 and 29. The Hossainy publication does not cure these defects. Claims 19 and 20 depend from independent claim 1 and include all of the elements and limitations of independent claim 1 and, thus, are allowable for at least the same reasons as those stated above for claim 1. Claims 36 and 37 depend from independent claim 29 and include all of the elements and limitations of independent claim 1 and, thus, are allowable for at least the same reasons as those stated above for claim 29. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claims 19, 20, 36 and 37 under § 103(a).

- I. Claim 28 has been rejected under 35 U.S.C. §103(a) as being unpatentable over the Schwartz publication in view of Hossainy

The Applicants traverse this rejection. Claim 28 has been cancelled. Applicants, therefore, request the withdrawal of the rejection of dependent claim 28 under § 103(a).

New Claims 41-53 are patentable

New claims 41-53 are patentable for at least the same reasons as stated above for pending claims 1-7, 9-20, 29-31 and 33-37. Independent claim 41 recites a hydrophilic polymer coating. The Schwartz publication alone or in combination with the prior art does not teach or suggest a hydrophilic polymer coating. Thus, claims 41-53 are allowable for at least the same reasons as claims 1-7, 9-20, 29-31 and 33-37.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

/Alan M. Krubiner, Reg. No. 26,289/
Alan M. Krubiner
Registration No. 26,289
Attorney for Applicant

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
Facsimile No.: (707) 543-5420